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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/729,856 | 12/04/2003 | Manne Satyanarayana Reddy | BULK 3.0-034 | 8301 |
| 45776 7590 03/25/2008 DR. REDDY'S LABORATORIES, INC. 200 SOMERSET CORPORATE BLVD SEVENTH FLOOR, BRIDGEWATER, NJ 08807-2862 | | | | |
| EXAMINER | | | | |
| LOEWE, SUN JAE Y | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1626 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/729,856

Applicant(s)

REDDY ET AL.

Examiner

SUN JAE Y. LOEWE

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-16 and 18-88 is/are pending in the application.
- 4a) Of the above claim(s) 8-16 and 24-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-7, 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 2-16 and 18-88 are pending in the instant application.

Response to Arguments

2. Applicant's arguments filed on December 19, 2007 have been fully considered but they are not persuasive. The following grounds of rejection are maintained:

- a) 35 USC 112 1st Paragraph Written Description (see response to arguments below, Section 4)
- b) 35 USC 112 1st Paragraph Enablement (see response to arguments below, Section 5)
- c) 35 USC 112 2nd Paragraph (see response to arguments below, Sections 6-7)
- d) 35 USC 102 (see response to arguments below, Section 8).

3. Applicant's arguments are successful in overcoming the 35 USC 112 2nd Paragraph rejection of the claims based on indefiniteness of the term "therapeutically effective amount." It is noted that the instant disclosure specifically defines "therapeutically effective amount." This ground of rejection is withdrawn.

Claim Rejections - 35 USC § 112 – 1st Paragraph

4. Written Description

Applicant argues:

.. It appears the Examiner suggests that the written description requirement necessitates inclusion of the entire X-ray pattern in the claims.

.....

It is well established in the law that the applicant is allowed to be own lexicographer. The Applicants have chosen to define the invention as a crystalline form of the compound having at least certain number of recited peaks. The Examiner is respectfully requested to set forth any law that prevents a patent applicant from doing so. ”

An x-ray diffraction pattern is a fingerprint that uniquely identifies a specific crystalline form. The presence and absence of peaks are important factors in establishing this fingerprint.

Applicant discloses crystalline forms identified by the XRD-pattern shown in Figure 1 or Figure 2 (ie. see claims 2 and 18). However, the claims require merely a few of the peaks shown in the XRD-pattern. Furthermore, the specification does not provide guidance or reasoning as to why an "abbreviated pattern" is sufficient to uniquely identify the claimed crystalline form.

Therefore, the claims are drawn to subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. Enablement

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Applicant argues:

„ An artisan is clearly instructed to take the explicitly described polymorphic form and put it together with clearly described excipients in the described manner. Thus, the issue of undue experimentation should not even arise. „

A *prima facie* case of made based on the preparation of a pharmaceutical composition comprising the specifically claimed crystalline form. See office action dated June 25, 2007.

Claim Rejections - 35 USC § 112 2nd Paragraph

6. Applicant argues:

„ Claims 2 and 18 have been rejected as allegedly indefinite for incorporating a figure by reference. According to the Examiner, Applicants should recite the peaks of the XRD pattern instead. „

Applicant is respectfully directed to page 4 of the office action dated June 25, 2007. See excerpts below:

" This rejection can be overcome by inserting the figure into the claims. "

7. Applicant argues:

„ The proper test is "whether or not one skilled in the art could determine specific values . . . based on the disclosure."

It is maintained that specific values cannot be determined for "prophylactically effective amount." The instant specification does not provide a definition for the term 'prophylactically effective amount.'

Claim Rejections - 35 USC § 102

8. Applicant argues:

„ The Examiner appears to suggest that the Examples of *Cossement* inherently anticipate the claimed polymorphic forms. ”

Applicant is respectfully directed to pages 11-12 of the office action dated June 25, 2007. See excerpts below:

“ As these forms differ from the claims in that the references are silent on the crystalline form, applicant must show that their crystalline form really is different from any of the ones prepared in the prior art. ”

.....

“ This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is. The only difference is a characteristic about which the reference happens to be silent. See also *Ex parte Anderson*, 21 USPQ 2nd 1241 and 1251, discussion of Rejection E. There, the decision states, “There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture.” (page 1253). ”

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe, Ph.D./
3-21-2008

/Kamal Saeed, Ph.D./
Primary Examiner
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